

Serial No. 10/501,773

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The Examiner rejected Claims 1, 2, 5, 20, 27 and 28 under 35 U.S.C. §102(b) as being anticipated by the teaching of *Gotsche et al.* (wo 00/18375, counterpart of US 6,579,953)²⁾ referring in particular to the statements found on page 1, indicated lines 5 to 12, page 4, indicated lines 3 to 11, page 19, indicated lines 10 to 34, and Example 7, of the international publication.³⁾

The Examiner acknowledged that the reference fails to expressly disclose a composition comprised of applicants' components (A), (B), and (C), but argued that a composition comprising components (A) and (C) was exemplified in the reference, and that the addition of a component (B) was envisaged.

To constitute anticipation, all material elements of the invention as claimed must be found in one prior art source.⁴⁾ More particularly, anticipation under Section 102 can be found only if a reference shows exactly what is claimed.⁵⁾ The test for anticipation is one of identity, which means that the reference must show the identical invention in as complete detail as is contained in the claim.⁶⁾ In fact, the Federal Circuit has stated that it is error to treat claims as a catalog of separate parts, in disregard of the part-to-part relationships set forth in the claims that give those claims their meaning.⁷⁾

The teaching of *Gotsche et al.* can not be deemed to meet these standards which were developed by the Courts for finding anticipation under Section 102. According to *Gotsche et al.* the "graft copolymers can be applied in pure form or else together with conventional excipients ... Examples of conventional excipients are colored pigments for coloring, white pigments such as titanium dioxide to increase hiding power, talc and silicon dioxide as non-stick agents, polyethylene glycols, glycerol, propylene glycol, triacetin, triethyl ci-

2) Unless otherwise indicated, the following remarks are made in relation to the U.S. counterpart of *Gotsche et al.*'s international application.

3) The referenced sections correspond to col. 1, indicated lines 10 to 13; col. 2, indicated line 66, to col. 3, indicated line 8, col. 11, indicated line 60, to col. 12, indicated line 15, and col. 17, indicated line 50, to col. 18, indicated line 20, of US 6,578,953.

4) Cf. *In re Marshall*, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Kalm*, 378 F.2d 959, 154 USPQ 10 (CCPA 1967).

5) Cf. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

6) Cf. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989).

7) Cf. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

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trate as plasticizer and various surface active substances ... to improve the wetting characteristics. ... All additives known to be suitable for gastric fluid-soluble film coatings can be used. It is also possible to combine the polymers used according to the invention with other film formers or polymers in the ratio from 1:9 to 9:1. Examples of polymers which can be employed for this purpose are ... "8) It is immediately apparent that the excipients as well as any additional polymers are optional ingredients rather than mandatory components. As such, the reference cannot be deemed to exactly show the specific combination of a polyvinyl alcohol polyether graft polymer (A) and polyvinyl alcohol (B) and a component (C) which is required in accordance with applicants' claims. *Gotsche et al.* merely generically disclose a plurality of additional polymers and state that the mentioned polymers or other polymers may be combined with a generic group of vinylester graft polymers which encompasses applicants' component (A). The disclosure of a genus is, however, insufficient to anticipate a species. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to even establish a prima facie case of obviousness.⁹⁾ In fact, the Federal Circuit has "decline[d] to extract from *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that . . . regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."¹⁰⁾

It is therefore respectfully requested that the rejection of Claims 1, 2, 5, 20, 27 and 28 under Section 102(b) based on the teaching of *Gotsche et al.* be withdrawn. Favorable action is solicited.

Further, the Examiner rejected Claim 7 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of *Gotsche et al.* (*ibid.*) when taken in view of the disclosure of *Cohen* (US 4,256,864). The Examiner argued in this context that it would have been obvious for a person of ordinary skill in the art to replace a polyvinyl alcohol of *Gotsche et al.*'s composition by a polyvinyl alcohol having a specific degree of hydrolysis as mentioned by *Cohen* because both *Gotsche et*

8) Cf. col. 11, indicated line 64, to col. 12, indicated line 21, of US 6,579,253; emphasis added.

9) *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.")

10) *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). See also *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

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al. and Cohen were concerned with coating compositions. Applicants respectfully disagree.

It is firstly re-emphasized that Gotsche et al. fail to specifically show the combination of a graft polymer with a polyvinyl alcohol and a color pigment. It is further respectfully pointed out that the formation of coatings for pharmaceutical dosage forms is by far too complex to consider any and all references dealing with "coatings" as being "analogous art". Notably, Gotsche et al. themselves point out that the excipients and implicitly also the polymers, have to be suitable for gastric fluid soluble films.¹¹⁾ It is well known in the art pertaining to coatings for pharmaceutical dosage forms that the substrate, as well as the intended point of delivery of the active ingredient, and correspondingly the conditions to which the dosage form is exposed until it reaches the intended point of delivery, have to be taken into consideration when a composition is modified. A reasonably person of ordinary skill would, therefore, not assume that one component of a certain first coating composition can arbitrarily be replaced by a compound which is useful in a second coating composition, particularly when the second coating composition serves a different purpose and/or is employed in a different environment.

Furthermore, it is necessary to appreciate the fact that, according to the disclosure of Cohen, polyvinyl alcohol is not employed as such. Rather, Cohen uses a complex of polyvinyl acetate which is formed in situ with a polymerization inhibitor, the polyvinyl alcohol and the inhibitor being bound in the complex in approximately equimolar amounts.¹²⁾ The coating solutions which are addressed in the disclosure of Cohen are generally obtained by mixing the polyvinyl alcohol with the polymerization inhibitor in amounts of polymer to inhibitor of 1:1 to 1:13, and specific coating solutions, such as e.g. disclosed in Example 1, are obtained from polyvinyl alcohol and bisphenol A salts. Also, the resulting solutions are employed to an inner surface of a polymerization reactor, and the adhesion of the coating layer to the reactor surface is believed to involve some type of electrical force or adsorption between the reactor surfaces and the complex.¹³⁾ It is further apparent that the respective layer is not easily or quickly dissolved considering that the subsequent polymerization which is conducted in the coated reactor is carried out in

11) Cf. col. 12, indicated lines 8 and 9, of US 6,579,953.

12) Cf. col. 3, indicated lines 44 to 62, of US 4,256,862.

13) Cf. col. 4, indicated lines 52 to 56, of US 4,256,864.

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water.¹⁴⁾ Considering the nature of Cohen's coating and the environment in which it is employed, a person of ordinary skill in the art to which the *Gotsche et al.* reference pertains could not reasonably expect to arrive at a useful coating composition by introducing the complex of Cohen into the coating of *Gotsche et al.* There is even less of an expectation of success when the modification of *Gotsche et al.*'s composition with only one of the components of the complex of Cohen's coating is contemplated.

Accordingly, it is respectfully urged that the rejection of Claim 7 under Section 103(a) based on the teaching of *Gotsche et al.* and the disclosure of *Cohen* be withdrawn. Favorable action is solicited.

Further, the Examiner rejected Claim 10 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of *Gotsche et al.* (*ibid.*) when taken in view of the disclosure of *Hendrickson et al.* (US 3,566,969). The Examiner argued in this context that a person of ordinary skill in the art would have been obvious for a person of ordinary skill in the art to employ certain N-vinylpyrrolidone polymers in the coating compositions of *Gotsche et al.* because *Hendrickson et al.* disclose that particular N-vinylpyrrolidone homopolymers have a variety of uses, including functioning as an adhesive and as a hardening agent in medicinal tablets.

Hendrickson et al. mention that N-vinylpyrrolidone polymers are useful as adhesives or hardening agents in medicinal tablets which aid the disintegration of the tablets when wetted. This is, however, not deemed sufficient to motivate a person of ordinary skill to consider any information conveyed by this reference to be of use in the context of coating compositions as addressed by *Gotsche et al.*'s teaching. The disclosure of *Hendrickson et al.* pertains to the gelling of organic polar liquids. It is mentioned that such gelled liquids can be used in cleaning and coatings. However, the reference is primarily concerned with the gelling of combustibles and explosives in order to improve their handling.¹⁵⁾ A person of ordinary skill would consider this to be an art which is completely different from the art pertaining to film coatings, and more specifically film coatings for pharmaceuticals.

Moreover, based on the statements of *Gotsche et al.* and the excipients which are mentioned in the primary reference, a person of

14) Cf. e.g. col. 6, indicated line 50, to col. 7, indicated line 43, of US 4,256,864.

15) Cf. col. 1, indicated lines 9 to 35, of US 3,566,969.

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ordinary skill in the art would not have been motivated to seek out an adhesive or a hardening agent to modify *Gotsche et al.*'s coating composition. The Examiner will note that *Gotsche et al.* refer to excipients which act as non-stick agents and as plasticizers. The collection of excipients which *Gotsche et al.* considered worth mentioning in the context of coatings comprising the graft copolymers addressed in the reference clearly conveys that a decrease in stickiness and/or hardness of the coating may be desirable whereas an increase in one or both of those properties is undesirable.

In light of the foregoing, it is respectfully requested that the rejection of Claim 10 under Section 103(a) based on the teaching of *Gotsche et al.* and the disclosure of *Hendrickson et al.* be withdrawn. Favorable action is solicited.

Additionally, the Examiner rejected Claim 11 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of *Gotsche et al.* (ibid.) when taken in view of the disclosure of *Stambaugh et al.* (US 4,146,489). The Examiner argued in this context that the references were analogous art because they address a similar problem, namely the formation of graft polymers with additives, and that it would therefore have been obvious to modify the coating compositions of *Gotsche et al.* by incorporating the N-vinylpyrrolidone alkyl methacrylate copolymers addressed in the *Stambaugh et al.* reference in order to improve the dispersancy and viscosity of *Gotsche et al.*'s coating composition. The Examiner's interpretation of what constitutes analogous art in the context of a determination under Section 103(a) appears to be in error. Two criteria have evolved for determining whether prior art is analogous:¹⁶⁾

- (1) whether the art is from the same field of the inventors endeavor, regardless of the problem addressed, and
- (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved,

Whether or not the two references are from a similar problem solving area is, therefore, of no concern in the determination whether the reference is analogous art or non-analogous art.

The disclosure of *Stambaugh et al.* pertains to lubricating oils and hydrocarbon fuels and is, as such, clearly not within the field of applicants' endeavor. Moreover, the disclosure of the reference

16) Cf. *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992).

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that polymethacrylates are excellent at influencing viscosity-temperature characteristics of lubricants can in no way be deemed to be reasonably pertinent to the particular problems encountered in the design of coating compositions which are, as provided by Gotsche et al.'s teaching, intended for pharmaceutical preparations. Also, the problem to be solved by applicants' invention is to provide more stable and flexible film coatings. The disclosure of Stambaugh et al. is therefore also not reasonably pertinent to applicants' particular problem. The combination of references in a determination under Section 103(a) is improper if one of the references is non-analogous art.¹⁷⁾ In other words, if a cited reference is non-analogous art, it has no bearing on the obviousness of the claim.¹⁸⁾ The Examiner's rejection of applicants' Claim 11 under Section 103(a) in light of the teaching of Gotsche et al. and the disclosure of Stambaugh et al. is therefore deemed to be in error.

It is accordingly respectfully requested that the rejection of Claim 11 under Section 103(a) be withdrawn. Favorable action is solicited.

The Examiner requested election of, and restriction of the application to, one of the following groups of claims:

- I) Claims 1 to 20, 27 and 28, drawn to a coating composition,; and
- II) claims 21 to 26, drawn to a method of using the respective coating composition.

Applicants herewith confirm the provisional election of group (I), ie. Claims 1 to 20, 27 and 28. It is also respectfully noted that newly added Claims 29 and 30 relate to coating compositions as claimed in Claim 1 and should therefore be grouped with the elected claims. Traversal of the Examiner's restriction requirement is, however, respectfully solicited in light of the following remarks.

The Examiner asserted that unity of invention was lacking because Claim 1 was anticipated and the respective subject matter could therefore not constitute the special technical features involved in the technical relationship between the claims of groups (I) and (II). In light of applicants' remarks regarding, in particular, the teaching of Gotsche et al. the Examiner's position is not deemed to be

17) In re Clay 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992).

18) Cf. Jurgens v. McKay, 927 F.2d 1552, 18 USPQ2d 1031 (Fed. Cir. 1991), cert. denied, 502 U.S. 902 (1991).

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well taken. Withdrawal of the restriction requirement is therefore respectfully solicited.

The Examiner further took the position that the claims were directed to more than one species of the generic invention, asserting that these species lacked unity of invention because they were not so linked as to form a single general inventive concept under PCT Rule 13.1. As concerns the Examiner's respective requirement to elect a species of component (B) and a species of component (C) applicants herewith confirm the provisional election of polyvinyl alcohols, polyvinylpyrrolidones and vinylpyrrolidone copolymers, in particular polyvinyl alcohols, for component (B), and color pigments or dyes for component (C).

The Examiner asserted that unity of invention was lacking because the alternatives in the definition of applicants' components (B) and (C) were not art recognized equivalents. However, nothing in PCT Rule 13 or the Administrative Instructions which explain the determination of unity of invention under the provisions of PCT Rule 13 suggests or implies that the alternative definitions of a technical feature have to be art recognized as equivalents. PCT Rule 13.2, for example, merely requires that one or more of the same or corresponding special technical features be involved in the technical relationship between claimed inventions if more than one invention is claimed. It is a part of applicants' invention that applicants' have found that the alternative denotations of component (B), or mixtures thereof, as well as the alternatives for component (C), or mixtures thereof, may be used in the specified amounts to provide the more stable and flexible film coatings.

The Examiner's position that the requisite species lack unity of invention is, therefore, not deemed to be well taken, and withdrawal of the respective restriction requirement is respectfully solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a two month extension of time be granted in this case. The respective \$450.00 fee is paid by credit card (Form PTO-2038 enclosed).

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MISCELLANEOUS FEES:

The fee for two additional depending claims in excess of 20 in the total amount of \$100.00 fee is paid herewith by credit card (Form PTO-2038 enclosed).

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,

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Encl.: CLAIM AMENDMENTS (Appendix I)

JR/BAS